ABSTRACT OF THE DISCLOSURE

The present invention provides methods for reducing the risks associated with administering adenoviral particles to subjects undergoing adenoviral gene therapy. In one aspect of the invention, at least one dose of adenovirus is administered to a subject to consequently allow the subject to mount an immune response against the adenovirus, the immune response allowing the subject to better tolerate gene therapy with a recombinant adenovirus containing a gene of interest. Preferably, the administered adenovirus is of the same serotype as the recombinant adenovirus to be used in gene therapy, or is of a serotype which is cross-reactive with the recombinant adenovirus serotype. In an alternate embodiment of the invention, a subject is provided with one or more doses of adenovirus-neutralizing antibodies administered prior to gene therapy with a recombinant adenovirus. In this aspect of the invention, parenteral administration of human antibodies or humanized antibodies is particularly preferred.

N:\2578\4257.1\pat app.wpd